

REMARKS

The Claims in the case are 2, 3, 4, 6, 12, 13, 15, 16, 27-28 and 31-33. Claim 2 has been amended in view of the previous deletion of C-2 from the definition of Z. Applicants reserve full rights to re-introduce the subject matter cancelled from the claims and claims themselves in this or any other application claiming the benefit of priority to the captioned application.

It is submitted that no new matter has been added by the above amendments.

Written Description Rejection

Claims 2, 3, 6, 12, 13, 15, and 27 were rejected under 35 USC §112, first paragraph, as containing subject matter that was not described in the specification in such a way to convey that the inventors, at the time the application was filed, had possession of the claimed invention. (Office action at page 2.) The Patent Office indicated that “this is a new matter rejection.” (*Id.*)

The Applicants respectfully traverses this rejection.

In making the rejection, the Patent Office contended that

“when n is 0, X is N, R² is hydrogen, R³ is a group of formula (b-1), Z is the heterocyclic ring system (c-2) or (c-4) wherein said heterocyclic ring system Z is attached to the rest of the molecule with a nitrogen atom, and R¹⁰ is hydrogen; then R⁴ is other than hydrogen, C₁-6alkyl or pyridinyl.”

The phrases in bold in currently amended claim 2 differ from the original claim 1 proviso. Applicants do not provide reasons for the differences, or how the specification as filed supports the identified proviso in currently amended claim 2.

(Office Action at page 2.)

As submitted in the previous paper submitted by the Applicants, amended claim 2 contains the following provision:

n is 0, X is N, R² is hydrogen, R³ is a group of formula (b-1), Z is the heterocyclic ring system (c-2) or (c-4) wherein said heterocyclic ring system Z is attached to the rest of the molecule with a nitrogen atom, and R¹⁰ is hydrogen; then R⁴ is other than hydrogen, C₁-6alkyl or pyridinyl.

The quoted language from the Office Action does not accurately reflect the actual language in amended claim 2. The bold terms “to the rest of the molecule” and

“hydrogen” were removed from the claim. R³ was amended to provide additional clarity.

It is respectfully submitted that (b-1) and Z are synonymous. Attention is directed to the instant specification at page 7, lines 5-8, and page 10, lines 37-38, to support this contention.

Nonetheless, Z has been replaced with (c-4) and it is believed the instant rejection is without merit and should be removed.

Indefiniteness Rejection

Claims 2, 3, 6, 10-16, 18, 19, 21, 22 and 24-27 were rejected under 35 USC §112, second paragraph. (Office Action at page 8.)

For the reasons set forth below, the rejection is traversed.

In making the rejection, the Patent Office contended that

Claim 2:

- It is not understood what is meant in the proviso by “Z is attached with a nitrogen atom.” Note that the definition of R³ shows that Z is a divalent moiety and there is no definition of what is attached to the Z extra valence. Further, it is not understood what is intended by “with a nitrogen atom.” It is not possible for Z to be attached by nitrogen, because the intended ring nitrogen is undefined. The ring nitrogen atom in Z has a hydrogen substituent and can support no further substituents. It is not possible for an extra nitrogen to be interposed between the Z moiety and R³, because such a structure is not provided for by formula (I) and such a structure would have unsatisfied nitrogen valences.

(Office Action at page 4.)

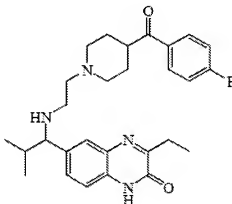
Z is no longer present in claim 2. Therefore, the instant rejection is moot. Nonetheless, solely in order to expedite prosecution on the merits, attention is directed to the bond in (c-4) that does not have R¹⁰ at one end. This bond indicates the point of attachment for (c-4). From this, it is believed that the term “attached with a nitrogen atom” is clear and withdrawal of the rejection is respectfully requested.

The Patent Office also contended that

The R6 definition "arylcarbonylpiperidiny(C1-6alkyl or arylC1-6alkyl)(C1-6alkyl)-aminoC1-6alkyl" is not understandable. The carbonyl-to-piperidiny attachment is undefined. It is unclear how the 3 C1-6 alkyl moieties are arranged in the last recited R6 definition. Are they in a single line or are 2 attached to the amino group?

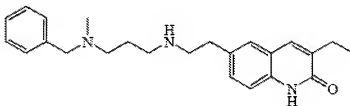
(Office Action at page 4.)

Applicants are confused by the Patent Office's question concerning whether the 3 C₁₋₆ alkyl groups were intended to be in a single line. If that were the case, it is submitted that the proper definition would be C₃₋₁₈alkyl, which is not what is in the claim. The claim is clear that there are 3 C₁₋₆ alkyl groups arranged as one skilled in the art would interpret them in view of the specification. Attention is directed to



compound 10

and compound 12



..... where the definition is visually depicted. It is believed that the rejection is without merit and should be withdrawn.

The Patent Office also contended that

- The Z moiety (c-2) is undefined.

(Office Action at page 4.)

The term (c-2) has been removed from the claims. With this amendment, it is believed the instant rejection is moot and should be withdrawn.

The Patent Office also contended that:

- The R10 definition “C1-6alkyloxyC1-6alkylamino” is not understandable. It is unclear how the two C1-6 alkyl moieties are arranged. Are they in a single line or are the oxy moiety and the C1-moiety 6 attached to the amino group?

(Office Action at page 4.)

Applicants refer to the discussion above concerning the R⁶ definition. The same can be said for R¹⁰. For this reason, the rejection is believed to be improper as it is clear what is intended by the claim language and withdrawal thereof is respectfully requested.

The Patent Office also contended that

- It is not understood what is intended by a “chemotherapeutic agent.” The specification recites cisplatin and bleomycin as chemotherapeutic agents (§¶ 0015). The specification also recites examples of chemotherapeutic agents that may be used in conjunction with radiosensitizers include, but are not limited to: adriamycin, camptothecin, carboplatin, cisplatin, daunorubicin, docetaxel, doxorubicin, interferon (alpha, beta, gamma), interleukin 2, irinotecan, paclitaxel and topotecan (§¶ 0156).

(Office Action at page 5.)

To reject a claim under the second paragraph of 35 USC § 112, it is incumbent on the Patent Office to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. This, the Patent Office has not done. The PTO has not made any factual determination that establishes that one of ordinary skill in the art “would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims” based upon the term “chemotherapeutic agent” as used in claims 12, 27, 28, and 33. In fact, the Patent Office readily found recitations of chemotherapeutic agents throughout the specification. It is believed that one of ordinary skill in the art would be able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims and the Patent Office has offered no facts to negate this proposition. For this reason alone, the rejection cannot stand and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, entry of the claims and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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